



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,695	09/25/2003	Wayne A. Jensen	DI-9-1	8741

26949 7590 07/25/2007
HESKA CORPORATION
INTELLECTUAL PROPERTY DEPT.
3760 ROCKY MOUNTAIN AVE
LOVELAND, CO 80538

EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
----------	--------------

1648

MAIL DATE	DELIVERY MODE
-----------	---------------

07/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/670,695

Applicant(s)

JENSEN ET AL.

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 108-113, 115-130 and 132-146 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 108-113, 115-130, and 132-146 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All. b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 May 2007 has been entered.

Claims 1-107, 114 and 131 have been cancelled. Claims 108-113, 115-130, and 132-146 are pending.

Claim Objections

Claim 108 is objected to because of the missing preamble of the claimed method. In the absence of a preamble, it is unclear whether step (3) achieves the desired result and whether claim 108 is the complete claimed method. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 108-113, 115-130 and 132-146 under 35 U.S.C. §103(a) as being obvious over Hofmann-Lehmann *et al.* (1996) in view of Prud'homme *et al.* (1997) and Maeda *et al.* (1997) is **withdrawn** in response to the amendment and **replaced by the following new rejection:**

Claims 108-113, 115-130 and 132-146 are rejected under 35 U.S.C. §103(a) as being unpatentable over Maeda *et al.* (1997) in view of Prud'homme *et al.* (1997) and Scott *et al.* (1999, IDS No. C14).

The instant claims are directed to a method comprising contacting a biological specimen with a recombinant protein comprising at least 300 contiguous amino acids from SEQ ID NO:18, SEQ ID NO:20 or SEQ ID NO:22 under conditions suitable for formation of a complex with an antibody, detecting the protein-antibody complex, and in the absence of the complex, vaccinating the animal against herpesvirus.

Maeda *et al.* disclose that gC is one of the most important subunit antigens in vaccine immunity for FHV-1 infection in cats and that monoclonal antibodies reacting with the gC can evaluate the gC antigen in vaccines (page 108, last ¶). Secondly, Maeda *et al.* disclose the nucleotide and amino acid sequence of a recombinant FHV type 1 (FHV 1) glycoprotein C (gC) protein (page 107) expressed in COS cells (page 106), which aligns with the instantly claimed SEQ ID NO:22 and differs from SEQ ID NO: 18 and 20 by one amino acid, from valine in SEQ ID NO: 18 or 20 to glycine, which is *prima facie* obvious since the minor change in chemical configuration or design of molecule discovered or made by applicants is *de minimis*, since there is no evidence that the change from valine to glycine of epitope is essential for immunogenic activity,

and since applicants have not explained practical advantages of any differences in the structure between claimed sequence and prior art. See Ex Parte Anderson 30 USPQ2d 1866 (Bd. Pat. App. & Int. 1993).

Maeda *et al.* do not disclose the detection of antibody:protein complex prior to vaccination.

Prud'homme *et al.* disclose a recombinant herpesvirus glycoprotein antigen, gp50 used in a competitive ELISA for detection in animal sera of antibodies of pseudorabies virus (PRV), an alphaherpesvirus (page 278, Materials and Methods). Prud'homme *et al.* further disclose that ELISAs, either as indirect or competitive formats, have been used to discriminate between naturally infected animals and those vaccinated with gene-deletion mutants.

Prud'homme *et al.* do not expressly suggest vaccination when not detecting the antibody-protein complex.

Scott *et al.* disclose a method to evaluate duration of immunity in cats vaccinated with a vaccine of feline panleukopenia virus (FPV), feline herpesvirus (FHV), and feline calicivirus (FCV) and specifically recommend that cats be revaccinated against FPV-FHV-FCV (Abstract).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the FHV-1 gC vaccine disclosed by Maeda *et al.* such that the same vaccine antigen is used in the detection of antibody-protein complex, as taught by Prud'homme *et al.*, and such that the presence or absence of the antibody-protein complex determines vaccination against FPV-FHV-FCV as suggested by

Art Unit: 1648


Scott *et al.* One having ordinary skill in the art would have been motivated to do to more accurately assess the immune status of the animal and identify the all animals in need of the FHV, FCV or FPV vaccine. this specific recombinant antigen since Maeda *et al.* explicitly suggests the application of this protein as an important subunit antigen in vaccine immunity for FHV-1 infection in cats (p. 108, last¶).

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.
Primary Examiner
12 July 2007



Louise Humphrey, Ph.D.
Assistant Examiner